**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| PHARMACEUTICAL RESOURCES, INC. and PAR PHARMACEUTICALS, INC., | : | |
| Plaintiffs, | : | Civ. No. 03-3357(DRD) |
| v. | : | **O P I N I O N** |
| ROXANE LABORATORIES, INC. | : | |
| Defendant. | : | |

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**Debevoise, Senior District Court Judge**

Plaintiffs, Pharmaceutical Resources, Inc., and Par Pharmaceutical, Inc. (collectively, "Par") instituted this patent infringement action against Roxane Laboratories, Inc., ("Roxane") alleging infringement of U.S. Patent No. 6,593,318 ("the '318 patent") and U.S. Patent No. 6,593,320 ("the '320 patent"). Roxane denied infringement and asserts that the '318 and '320 patents are invalid and unenforceable. A Markman hearing was held to determine the meaning of disputed claim terms. Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996).

## I. Background

The '318 and '320 patents are directed to stable flocculated suspensions of megestrol acetate and methods for using and manufacturing such suspensions. Megestrol acetate is used to stimulate the appetite of patients suffering severe weight loss, such as patients suffering from advanced AIDS or undergoing chemotherapy. Megestrol acetate can be administered as a capsule or tablet. High doses are required to achieve significant appetite stimulation. It is difficult for patients, particularly those suffering from loss of appetite, to swallow large numbers of capsules or tablets. Providing megestrol acetate in liquid form enables a patient to get an effective dose comfortably.

Problems were encountered in formulating megestrol acetate in liquid form. Megestrol acetate is highly insoluble in water and therefore particles of the drug will sink toward the bottom of the container, rendering doses that may be too high or too low to be safe and effective. The preferred dosage form is a liquid suspension whereby the solid megestrol acetate particles can be resuspended relatively evenly in liquid.

Megestrol acetate presents a particular problem in this regard. Because the surface energy of megestrol acetate particles is lower when they contact one another than when they contact water, megestrol acetate particles form a hard cake when they settle that cannot be easily redispensed by shaking. In addition, particles of megestrol acetate entrap over on their surface making it particularly difficult to mix the particles into water. A surface agent, known as a surfactant is required in the formulation to reduce interfacial surface tension of the particles and allow them to be mixed into the suspension.

It is an object of the '318 and '320 patents "to provide a liquid composition of megestrol acetate in the form of a flocculated suspension" ('318 patent; col. 3, l 2-4; '320 patent, col. 3, l 20-22). The claimed discovery was that such a suspension could be formed by using any surfactant in combination with one or more wetting agents, specifically polyethylene glycol, propylene glycol, glycerol and sorbitol.

Among the claims that Roxane is alleged to have infringed are independent claims 19 and 41 of the '318 patent and claim 1 of the '320 patent. The asserted claims of the '318 patent cover stable flocculated suspension of megestrol acetate where megestrol acetate is combined with one or more of the wetting agents referred to above and a surfactant. Independent claim 19 of the '318 patent recites:

> An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising:
>
> (a) megestrol acetate;
>
> (b) at least two compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and
>
> (c) a surfactant

Independent claim 41 recites:

> An oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising:
>
> (a) megestrol acetate;
>
> (b) at least one compound selected from the group consisting of propylene glycol, glycerol, and sorbitol; and
>
> (c) a surfactant.

Par alleges Roxane's product infringes these claims, as well as dependent claims 20, 25, 26, 27, 32, 35, 42, 47, 48, 49 and 53.

The asserted claims of the '320 patent are directed to methods of manufacturing megestrol acetate suspensions. Independent claim 1 recites:

> A method of preparing an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising:
>
> forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant, provided that the combination does not consist of polyethylene glycol and polysorbate; and combining the solution with megestrol acetate.

Par alleges that Roxane's manufacturing process infringes this claim as well as dependent claims 2, 6 and 7.

The parties contend for different meanings of the term "stable flocculated suspension" and other terms as those terms appears in claims 19 and 41 of the 318 patent and as they appear in claim 1 of the '320 patent. In particular:

1. Roxane contends that in all claims "flocculated suspension" means "a suspension of uniformly dispersed solid matter, in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each closely, the open network aggregate, over time, forming a loosely packed sediment with scaffold-like structure, and not a solid cake."

Par contends that a "stable flocculated suspension" means "a suspension that resists caking and is redispersable after settling, wherein individual insoluble particles form open network aggregates. Stable flocculated suspensions are not limited to suspensions that exhibit the stability of commercially viable suspensions, such as those disclosed as preferred embodiments of the '318 and '320 patents."

2. Roxane contends that in all claims the term "stable," which modifies the phrase "flocculated suspension," means "the flocculated suspension, upon sedimentation after storage at 40°c and 75% relative humidity for a period of three months, can be shaken to reform the original, uniformly dispersed, flocculated suspension."

Par contends that the claims contain no such temperature, humidity and time limitations and relies on its definition of "stable flocculated suspension."

3. Roxane contends that in claims 19 and 41 of the '318 patent, the phrase "an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising . . . (b) at least two compounds selected from the group consisting of polyethylene glycol, propylene

glycol, glycerol, and sorbitol; and (c) a surfactant" means: "the surfactant and component (b) must each be present in sufficient quantity to form a stable flocculated suspension."

Par asserts that claims 19 and 41 have no such function or quantity limitation.

4. Roxane contends that the comparable language in claim 1 of the '320 patent means "component (a) [the wetting agents] and the surfactant must each be present in sufficient quantity to form a stable flocculated suspension."

Par asserts that claim 1 of the '320 patent, like claims 19 and 41 of the '318 patent, does not have such function or quantity limitation.

5. Roxane contends that in claim 1 of the '320 patent, the claim limitation "forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant . . . ; and combining the solution with megestrol acetate" means "components (a) and the surfactant must be added to the water before the addition of megestrol acetate."

Par contends that, properly interpreted, the plain language of claim 1 of the '320 patent contains no requirement that component (a) and the surfactant be added to the water before the addition of megestrol acetate.

## II. Discussion

A. Legal Standards: In the recent case of Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit articulated at some length general principles of claim construction. Under Markman, of course, claim construction presents a question of law to be resolved by the court. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" Phillips, 415 F.3d at 1312. Further, "the

words of a claim 'are generally given their ordinary and customary meaning.'" and "the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id. The court "'cannot look at the ordinary meaning of the term . . . in a vacuum. Rather, [it] must look at the ordinary meaning in the context of the written description and the prosecution history.'" Id.

The Court noted that "[b]ecause the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.' Those sources include 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" Id. at 1314 (citations omitted).

By way of further guidance, the Court suggested that "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term. Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims. Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example, the presence of a dependent claim that adds a particular

limitation gives rise to a presumption that the limitation in question is not present in the independent claims." Id. at 1314-15 (citations omitted).

Referring specifically to the specification, the Court noted that "the specification 'is always highly relevant to the claims construction analysis. Usually, it is dispositive; it is the best single guide to the meaning of a disputed term'. . . 'The specification is, thus, the primary basis for construing claims.' On numerous occasions since then, we have reaffirmed that point, stating that 'the best source for understanding a technical term is the specification from which it arose, informed, as needed, by the prosecution history." Id. at 1315 (citations omitted). Despite the importance of the specification the Court referred to Texas Digital Systems, Inc., v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002), which noted "'one of the cardinal sins of patent law - reading a limitation from the written description into the claims.'" Id. at 1319.

Referring to the prosecution history, the Court stated that "[i]n addition to consulting the specification, we have held that a court should also consider the patent's prosecution history, if it is in evidence.' . . . Furthermore, like the specification, the prosecution history was created by the patentees in attempting to explain and obtain the patent. Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of their negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id. at 1317 (citations omitted).

The Federal Circuit has "also authorized district courts to rely on extrinsic evidence, which 'consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.' However, while extrinsic evidence 'can shed useful light on the relevant art,' we have explained that it is 'less significant than the

intrinsic record in determining the legally operative meaning of claim language.' Within the class of extrinsic evidence, the court has observed that dictionaries and treaties can be useful in claim construction. We have especially noted the help that technical dictionaries may provide to a court 'to better understand the underlying technology' and the way in which one of skill in the art might use the claim terms. Because dictionaries, and especially technical dictionaries, endeavor to collect the accepted meanings of terms used in various fields of science and technology, those resources have been properly recognized as among many tools that can assist the court in determining the meaning of particular terminology to those of skill in the art of the invention." Id. at 1317-18 (citations omitted).

As a cautionary note, the Federal Circuit stated that "[w]e have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms. . .. In sum, extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of the patent claim scope unless considered in the context of the intrinsic evidence." Id. at 1318-19.

As the Court explained, "[t]he sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." Id. at 1324.

With these principles in mind the court will attempt to resolve the parties' disputes about the meaning of the claim language.

B. Stable Flocculated Suspension: Putting aside for the moment the meaning that Roxane attributes to "stable," the meaning of "flocculated suspension" will be addressed. Each of independent claims 19 and 41 of the '318 patent and independent claim 1 of the '320 patent

include that term. The parties agree, and the patent states, that a suspension is made up of a particulate matter suspended uniformly in a medium but not soluble in it ('318 patent, col 3, lines 36-37; '320 patent, col 3 lines 56-57). Suspensions are important when formulating drugs that are insoluble in conventional solvents such as water. When in suspension the drug remains dispersed in solid form in the solvent. The problem, such as that addressed in the patents in issue, is to prevent the drug particles when they settle from forming a hard cake that cannot be redispersed.

The patents at issue solve this problem with respect to megestrol in the following manner:

> Individual solute molecules do not bond tightly to form a cake in a flocculated suspension due to the fact that they form an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely. Flocculated suspensions have a high sedimentation height, due to the natural tendency for an open network aggregate to not form a cake. The resulting sediment is loosely packed and possesses a scaffold-like structure. Particles do not bond tightly to each other and a hard, dense cake does not form. Therefore, the sediment is easy to redisperse, so as to reform the original suspension. These properties make the flocculated suspension very desirable, particularly for liquid pharmaceutical formulations.

('318 patent, col. 3, l. 37-51; '320 patent, col 3, l. 56 to col. 4, l. 4).

It is Roxane's contention that a flocculated suspension as used in the claims includes only a particular type of suspension of uniformly dispersed solid matter, namely, one in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network, over time, forming a loosely packed sediment with a scaffold-like structure, and not a solid cake.

Par contends that Roxane's proposal that flocculation necessarily requires that the open network aggregate over time, to form a loosely packed sediment finds no supports in the claims

nor does Roxane's proposed requirement that formation of a sediment be a necessary characteristic of flocculation.

Stating the issue in practical terms, Roxane contends that flocculated suspension, as defined in the claims, does not extend to other types of pharmaceutical suspensions, in particular a structured vehicle, which avoids formation of hard cake. According to Roxane, the pertinent patent claims describe a flocculated suspension as one which results in a loosely packed sediment with a scaffold-like structure, while a structured vehicle involves a stable suspension in which the suspended particles are in a state of more or less permanent suspension, never forming a sediment that is re-flocculated by vigorous shaking.

To resolve this issue it is useful to examine the claims and specification in the context of the pharmaceutical art in which the controversy arises. Both parties refer to, and rely on, Robert A. Nash, Pharmaceutical Suspensions, in Pharmaceutical Dosage Forms: Dispense Systems Vol 1 and Vol 2 (Herman A. Lieberman, et al., eds 1996). Nash writes, "Flocculation refers to the formation of a loose aggregation of discrete particulars held together in a networklike structure . . . The floccule referred to as a 'stable floc' usually contains varying amounts of entrapped liquid medium or vehicle within the networklike structures." (Nash Vol 2 p. 18).

Nash cites the chief advantages of a stable floc as "1.[t]he aggregates tend to break up easily under the application of small amounts of shear stress, such as gentle agitation of a bottle or vial . . . Flocculation, therefore, imparts a structure to the suspension with virtually no increase in viscosity." "2. [i]n contrast to peptized or deflocculated systems, the stable floc will settle rapidly, usually to a high sediment volume, and may be easily resuspended even after standing for prolonged periods of storage. . ." (Nash Vol. 2 p. 19).

Nash notes that there are several methods of producing flocculated pharmaceutical suspensions. He refers to one of these as "controlled flocculation procedures" (Nash Vol 2, p. 20-21). These all appear to contemplate the appearance of a sediment and the avoidance of caking.

Distinct from these methods is the "structured vehicle" method which Nash describes as follows:

> The final approach to the preparation of a stable suspension is based on the concept of the "structured vehicle," in which the viscosity of the preparation, under static conditions of very low shear on storage, approaches infinity. The vehicle is said to behave like a "false body" which is able to maintain the suspended particle in a state of more or less permanent suspension.
>
> Structured vehicles are not normally considered for the preparation of parenteral suspensions: because of their high viscosity, such systems lack sufficient syringeability for ease of use.

Nash, Vol 2 p. 22.

There is a discussion of both flocculation and methods of achieving flocculation in Sworbrick, J., Coarse Dispersions in Remington: The Science and Practice of Pharmacy, 19th Ed. 1995 Vol. 1. He first notes that "[t]he pharmaceutical formulator is concerned primarily with producing a smooth, uniform, easily flowing (pouring or spreading) suspension or emulsion in which dispersion of particles can be effected with minimum expenditure of energy." Id. at 278. Further, "[a] pharmaceutical suspension may be defined as a coarse dispersion containing finely divided insoluble material suspended in a liquid medium." Id. He added:

> There are certain criteria that a well-formulated suspension should meet. The dispersed particles should be of such a size that they do not settle rapidly in the container. However, in the event that sedimentation does occur, the sediment must not form a hard cake. Rather, it should be capable of redispersion with a minimum of effort on the part of the patient. Finally, the product should be easy

> to pour, have a pleasant taste and be resistant to microbial attack.
> The three major concerns associated with suspensions are (1) ensuring adequate dispersion of the particles in the vehicle, (2) minimizing settling of the dispersed particles and (3) preventing caking of these particles should a sediment form. Much of the following discussion will deal with the factors that influence these processes and the ways in which they can be minimized.

Id. at 279

Sworbrick noted that, although some workers in the field use "flocculation" differently, in his article "the term flocculation is used for all aggregation processes irrespective of mechanism." Id. He further noted that the "formulation of a suspension possessing optimal stability depends on whether the particles in suspension are to be flocculated or to remain deflocculated." He described three methods of obtaining a suspension of optimal stability - controlled flocculation as a means of preventing cake formation upon sedimentation, structured vehicles whereby flocculated particles are supported in a structured vehicle and a combination of those two methods.

Patel, N. et al., Pharmaceutical Suspensions, in THE THEORY AND PRACTICE OF INDUSTRIAL PHARMACY, 3rd Ed., 1986 (Lachman, L. et al. Eds) at 481-484 states:

> Although there have been several attempts in the literature to clarify the imprecise terminology used to describe aggregation phenomena, the problem of definition is formidable. The terms used in the colloid science and pharmaceutical science do not coincide, and to make matters worse, individual workers tend to use the terms "flocculation," "coagulation," and "aggregation" interchangeably. Regardless of the mechanism of aggregation, it is convenient to classify the end result of the aggregation of suspended particles on the basis of the morphological characteristics of the aggregate.
>
> Note first the open network aggregate or floccule. This aggregate is characterized by a fibrous, fluffy, open network of aggregated particles. *Id.* at 482-483.

Thus a review of the literature suggests that "flocculation" per se had a plain and ordinary

meaning at the time of Par's invention, that is, loose or open aggregations of particles regardless of the mechanism that formed the aggregation. The issue, therefore, is whether the invention claimed in the '318 and '320 patents is limited to a particular method of achieving a stable flocculated suspension and to the product of such a method.

Roxane would define "stable" separately from "flocculated suspension". Specifically, a "stable" suspension is that kind of a suspension that can be shaken to reform the original, uniformly dispersed flocculated suspension, after storage at 40°c and 75% relative humidity for a period of three months. Roxane derives this limitation from Example 4 in the common specification, entitled "Suspension Stability."

> The tendency of each suspension, prepared according to Example 1-3, to flocculate was assessed as follows. Each suspension is allowed to settle in a controlled environment of 40°c, and 75% relative humidity for a period of 3 months. Following that, each of the sedimented suspensions was shaken and easily redispersed reforming the original suspension.

(A5, '318 patent, col. 7, lines 29-38; A12, '320 patent, col. 8, lines 9-19).

Further, Roxane finds support for its definition of "stable" in the prosecution history of the patents.[1] During the prosecution of the '241 application, which is the grandparent of the

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[1] The '318 patent issued on July 15, 2003 from a patent application filed in the U.S. Patent and Trademark Office ("PTO") on January 9, 2001. The '320 patent issued on July 15, 2003 from a patent application filed in the PTO on April 30, 2002. Both patents are titled "Flocculated Suspension of Megestrol Acetate" and both patents have the same specification. The '318 patent claims stable flocculated suspensions of megestrol acetate, and the '320 patent claims a method of making such compositions.

The series of patent applications which resulted in issuance of the '318 patent is described on the first page of the patent (A1). It shows that the '318 patent issued from patent application Serial No. ("S/N") 09/757,261 filed on January 9, 2001 ("the '261 application"), which was a "continuation" of an earlier application, S/N 09/416,841, filed April 20, 1998 ("the '241 Application"). As is evident from the first page of the '320 patent (A8), the sequence of applications which led to issuance of the '320 patent is the same, except that it issued from S/N 10/136,823 ("the '823 Application"), filed April 30, 2002, which was a "division" of the '261

application that issued as the '318 patent and the great grandparent of the application that issued as the '320 patent, in response to a rejection of all pending claims under 35 U.S.C. § 112, the inventors stated:

> The Examiner rejected claims 1-22 under 35 § 112, second paragraph, allegedly because the claims comprise formulas whose stability is not of a definite range.
>
> In response, applicants have herein above amended claim 1 to indicate that a stable flocculated suspension in water is a suspension capable of being redispersed after being allowed to settle at 40°c and 75% relative humidity for a period of three months. Accordingly, the Examiner is kindly requested to withdraw this rejection.

(Page 3 of September 29, 1999 Amendment in '241 application). Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1349 (Fed. Cir. 2004) ("[T]he prosecution history of one patent is relevant to an understanding of the scope of a common term in a second patent stemming from the same parent application").

Roxane argues that having thus defined stability, Par cannot assert a different meaning for that term in the suit patents, and that accordingly, the only way to understand the term "stable" as used in the claims of the suit patents is as described by the inventors, namely, that following sedimentation upon storage at 40°c and 75% relative humidity for a period of three months, the sedimented suspension can be shaken to reform the original, uniformly dispersed suspension.

Roxane's attempt to narrow the meaning of stable flocculated suspension by attributing a special limitation to the word "stable" is not supported by the language of the claim or the intrinsic evidence. Claims 19 and 41 of the '318 patent and claim 1 of the '320 patent do not include the 40°c and 75% relative humidity limitation. Despite the fact that Example 4 (with its

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Application.

reference to Examples 1-3) refers to a specific controlled environment, the balance of Example 4 makes clear that the claims are not limited to the controlled environment used in the Examples: "The invention has been described in terms of preferred embodiments thereof, but is more broadly applicable as will be understood by those skilled in the art. The scope of the invention is therefore limited only by the following claims." ('318 patent, col. 7, ll 39-42; '320 patent, col. 8, ll 21-24).

The prosecution history does not support Roxane's position. Although claims in the '065 "grandfather" patent were narrowed to recite the 40°c and 75% relative humidity limitations, in the ongoing negotiations between the PTO and Par's inventors the inventors broadened the claims in the '318 and '320 patents to include both stable flocculated suspensions with the 40°c and 75% relative humidity limitations ('318 patent, claims 36-40 and 54-58) and stable flocculated suspensions without that limitation ('318 patent, claims 19 and 41). The examiner allowed these broader claims. "Differences among claims can also be a useful guide in understanding the meaning of particular claim terms. For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1314-15 (citations omitted).

Neither the language of the claims, nor the specification nor the prosecution history support Roxane's contention that the use of the term "stable" in "stable flocculated suspension" incorporates into the respective claims a limitation that flocculation must occur after storage at 40°c and 75% humidity for a period of three months.

Probably the most critical interpretive question is whether "stable flocculated suspension" means, as Par contends "a suspension that resists caking and is reversible after settling, wherein

individual insoluble particles form open network aggregates. Stable flocculated suspensions are not limited to suspensions that exhibit the stability of commercially viable suspensions, such as those disclosed as preferred embodiments of the '318 and '320 patents;" or, on the other hand, whether "stable flocculated suspension" means, as Par contends "a suspension of uniformly dispersed solid matter, in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network aggregate, over time, forming a loosely packed sediment with a scaffold-like structure and not a solid cake."

Par's definition, according to Par, is broad enough to embrace a structured vehicle such as the accused formulation in this case. Roxane's definition, according to Roxane, is limited to flocculated suspensions in which the solid matter forms an open network aggregate which, over time, forms a loosely packed sediment with a scaffold - like structure and not a solid cake. A structured vehicle does not result in the formation of a loosely packed sediment; rather its solid matter remains permanently in a uniformly dispersed suspended state, held there by the nature of the substance in which it is dispersed.

The language of the claims does not specifically exclude a structured vehicle approach. In such an approach there is a pharmaceutical composition; it is referred to in the art at least occasionally as a form of stable flocculated suspension in water and it might well include (a) megestrol acetate, (b) at least two [or one] of the compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (c) a surfactant.

Applying the teaching of Phillips, the words of a claim are generally given their ordinary and customary meaning, that is, the meaning that the term would have to a person of ordinary

skill in the art in question at the time of the Invention. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Phillips, 415 F.3d at 1313. Two admonitions confront the construing court: First, "the specification 'is always highly relevant to claims construction analysis. Usually, it is dispositive, it is the best single guide to the meaning of a disputed term' . . .' The specification is, thus, the primary basis for construing claims . . .'" Id. at 1315. Second: the court must not commit "one of the cardinal sins of patent law - reading a limitation from the written description into the claims." SciMed Life Systems v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1340 (Fed. Cir. 2001).

With these admonitions in mind the court will turn to the specification of each of the two patents in issue to determine whether the term "stable flocculated suspension" as used in the claims is broad enough to encompass suspensions derived from processes other than those described in the specification examples, which involve formation of a sediment which is not subject to caking.

Although the Summary of the Invention contains no language that limits the generality of the term "stable flocculated suspension," the Detailed Description of the Invention describes throughout a product and/or a method that involves formation of a sediment that does not cake and that can be flocculated by shaking.

In the common specification shared by the '318 and '320 patents, the inventors describe their invention as follows:

> In accordance with the invention, a flocculated suspension of megestrol acetate

> can surprisingly be formulated in the presence of any surfactant and at least one compound selected from the group consisting of polyethylene glycol, proplylene glycol, glycerol, and sorbitol. [‘318 patent, col. 3, ll. 31-35; ‘320 patent, col. 3, ll. 51-55].
>
> …
>
> What is surprising about the present invention is that any surfactant can effectively wet megestrol acetate and together form a stable flocculated suspension in the presence of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol. The surfactant can be anionic, cationic, or non-ionic. [‘318 patent, col. 4, ll. 5-9; ‘320 patent, col. 4, ll. 30-37].
>
> The presence of at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol is critical to the suspendability of megestrol in a flocculated composition. [‘318 patent, col. 5, ll. 11-14; ‘320 patent, col. 5, ll. 44-48].

In the common specification of the suit patents, the inventors explain what they mean by “flocculated suspension”:

> Individual solute molecules do not bond tightly to form a cake in a flocculated suspension due to the fact that they form an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely. Flocculated suspensions have a high sedimentation height, due to the natural tendency for an open network aggregate to not form a cake. The resulting sediment is loosely packed and possesses a scaffold-like structure. Particles do not bond tightly to each other and hard, dense cake does not form. Therefore, the sediment is easy to redisperse, so as to reform the original suspension. These properties make the flocculated suspension very desirable, particularly for liquid pharmaceutical formulations.

(‘318 patent, col. 3, ll. 37-51; ‘320 patent, col. 3, ll. 56 to col. 4).

The following paragraph of the specification describes a deflocculated suspension and formation of cakes and the consequence of caking; “When a hard cake is formed, it is difficult, if not impossible, to redisperse. (‘318 patent, col. 3, ll 64-65; ‘320 patent col. 4, ll. 21-22).

Use of a structured vehicle does not contemplate settling to form a sediment. Rather, by

virtue of the nature of the liquid in which the megestrol is suspended, there is permanent suspension of the flocculated particles. Arguing that the claim term encompasses the structural vehicle form of flocculation, Par points to language in the common specification which suggests the utility of using a suspending agent: "Conventional pharmaceutical carriers can be present. Xanthan gum is preferably used as a suspending agent . . . The use of a suspending agent maintains the megestrol acetate particles in a uniformly suspended state for a longer period of time during the dose administration period thereby permitting uniform dosing. Xanthan gum is a high molecular weight polysaccharide having thixotropic properties with immediate viscosity recovery." ('318 patent, Col 5, ll 23-31; '318 patent, Col 5, ll 56-64). Although use of Xanthan gum prolongs the state of suspension, it in no way is suggested as a means of creating a permanent suspension; rather its use is suggested as a means of prolonging the suspended state before sedimentation occurs.

The common specification contains three formulations (Examples 1, 2 and 3) of flocculated suspensions of megestrol acetate, each differing from the others by only one or two ingredients. The common specification also describes the method used to make the formulations of the Examples. As described in the common specification, the method used to make the suspensions of the Examples has the following sequence of steps:

- Any one or more polyethylene glycol, propylene glycol, glycerol and/or sorbitol and a surfactant are combined in water to form a solution.
- Xanthan gum is added to this solution to uniformly hydrate the gum.
- Citrates and flavor are added to the dispersion and the slurry is passed through a screen.
- Megestrol acetate is added to the dispersion to provide a uniform

suspension.

- The entire suspension is passed through a colloid mill or homogenizer to produce the final product, a stable, flocculated suspension of megestrol acetate.

('318 patent, col. 5, l. 54 to col. 7, l. 27; '320 patent, col. 6, l. 32 to col. 8, l. 7).

> Stability of the suspensions of Example 1-3 is described in Example 4.
>
> Suspension Stability
>
> The tendency of each suspension, prepared according to Examples 1-3, to flocculate was assessed as follows. Each suspension is allowed to settle in a controlled environment of 40°c and 75% relative humidity for a period of 3 months. Following that, each of the sedimented suspensions was shaken and easily redispersed reforming the original suspension.

('318 patent, col. 7, ll. 29-38; '320 patent, col. 8, ll. 10-19).

It has previously been determined that the controlled environment of 40°c and 75% relative humidity for a period of 3 months is not part of the claim term. However, all four of the examples contemplate sedimented suspensions which can be reflocculated by shaking. In view of the language following the examples to the effect that the invention is more broadly applicable than the preferred embodiments thereof, the examples alone might be insufficient to confine "stable flocculated suspension" as used in the claims. However, the examples serve to confirm the language of the description. That language conveys to a person skilled in the art that the claimed invention is the formation of a stable flocculated suspension in which the drug particles are allowed to settle to form a sediment, but in which the nature of the resulting sediment is controlled such that formation of a hard cake is avoided.

Par argues strenuously that this construction of "stable flocculated suspension" ignores how that phrase is used in the asserted claims and commits one of the "cardinal sins" of claim

construction of importing limitations from the specification into the claims. In SciMed the Court addressed the contention that in construing the claims based on the written description, the district court committed this cardinal sin. Rejecting this argument, the court stated:

> As this court has recently explained, "[o]ne purpose for examining the specification is to determine if the patentee has limited the scope of the claims." Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims read without reference to the specification, might be considered broad enough to encompass the factors in question.

242 F.3d at 1341 (citation omitted).

In the present case even though the language of the claims, read without reference to the common specification, might be considered broad enough to encompass a stable flocculated suspension of any character, a person skilled in the art upon reading the description in the specification (as illustrated in the examples) would understand that the invention is limited as recited above.

C. Effect of Surfactant and Wetting Agents: Roxane contends that in claims 19 and 41 of the '318 patent the phrase "an oral pharmaceutical composition in the form of a stable flocculated suspension in water comprising . . . (b) at least two compounds selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol; and (c) a surfactant" means: "the surfactant and component (b) must each be present in sufficient quantity to form a stable flocculated suspension." Roxane also contends that the comparable language in claim 1 of the '320 patent means "component (a) [the wetting agents] and the surfactant must each be present in sufficient quantity to form a stable flocculated suspension.

The language of the claims themselves does not impose the requirement for which Roxane contends. There is nothing in the specification that imposes a quantity or function requirement on each of the two categories of components listed in these claims. Other claims do contain quantity limitations. For example, claim 26 depends from claim 19, and includes the limitation that the total concentration of the Markush group elements present "is up to 40% weight/volume." ('318 patent, col. 8, ll. 54-57). The absence of a quantity limitation in claim 19 is significant and must have been intended. Other examples need not be recited.

Similarly, the specification calls for the presence, not specific quantities of the two categories of components. ('318 patent, col. 4, ll. 5-10; col. 5, ll. 11-15). The preferred embodiments are in this context, as in the context of construing "stable," simply examples of formulations prepared according to the invention.

There is no basis for Roxane's proposed claim construction, and it will be rejected.

D. Order of Combination: Roxane contends that in claim 1 of the '320 patent the claim limitation "forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant . . .; and combining the solution with megestrol acetate" means "components (a) and the surfactant must be added to the water before the addition of megestrol acetate." Par contends that the claim language imposes no such order of preparation when formulating the final product.

Roxane notes that a wetting agent is required to assist in dispersing an insoluble substance (such as megestrol acetate) in water and that: "[t]o achieve that result, the wetting agent must be present in the water before the insoluble substance is added. If the insoluble substance were added to the water before the wetting agents, the insoluble, unwetted substance

would clump and not disperse properly. It is only by first dispersing the wetting agents in the water and then adding the insoluble substance that the insoluble substance can be made to disperse throughout the water. This further supports a claim construction of claim 1 of the '320 patent that requires the wetting agents, i.e., components (a) and (b) of claim 1, to be added to the water to form a solution before the megestrol acetate is added." (Roxane's Opening Brief at pp. 17-18). In further support of its position Roxane points to the three Examples in the specification in which the order of mixing followed that specified in claim 1 of the '320 patent.

Par contends that Roxane's argument that "if the solution is not already formed by combining water with components (a) and (b), it would be impossible to perform the final step, 'combining the solution with megestrol acetate'" is flawed. The specification discloses that "any surfactant can effectively wet megestrol acetate and together form a stable flocculated suspension in the presence of at least one compound selected from the group polyethylene glycol, etc., '320 patent, col. 4, ll. 30-36. The wetting is accomplished because "the hydrophobic group of the surfactant is sequestering the megestrol [acetate] while the hydrophilic group of the surfactant is solubilized in the bulk water" Id. col. 5, ll 2-5. The surfactant alone is all that is required to wet the megestrol acetate. This negates Roxane's functional argument supporting its construction of claim 1. As was the case when construing "stable," the Examples are not by themselves claim limitations, and the fact that a particular order of mixing is employed in them does not preclude a different order of mixing.

Par's most difficult hurdle is the language of the claim itself. Because the claim recites steps in a particular order, the claim construction is not limited to that order unless grammar, logic or the written description itself requires the steps be performed in that order. Bell Comm.

Res., Inc. v. Fore Sys. Inc., Nos. 02-1083 and 02-1084, 62 Fed. Appx. 951, 955 (Fed. Cir. March 27, 2003). Neither logic nor the written description require that the component (a) (sometimes referred to as the "Markush" group elements) and the surfactant be added before the solution is combined with megestrol acetate. However, the grammar of claim 1 clearly does require a specific order of mixing:

> forming a solution by combining water with (a) at least one compound selected from the group consisting of polyethylene glycol, propylene glycol, glycerol, and sorbitol, and (b) a surfactant, provided that the combination does not consist of polyethylene glycol and polysorbate; and combining the solution with megestrol acetate.

Par engages in grammatical gymnastics in an attempt to establish that this language does not require first, the creation of the solution and then combining the solution with megestrol acetate. These efforts are not persuasive, and Par must live with the unambiguous language of its claim as written by it.

## III. Conclusion

To summarize, the court resolves the various claim construction issues as follows:

A "stable" flocculated suspension as used in the patent claim is not limited to a suspension that can be shaken to reform the original, uniformly dispersed flocculation suspension, after storage at 40°c and 75% relative humidity for a period of three months.

A "stable flocculated suspension" as used in the patent claims means a suspension of uniformly dispersed solid matter, in which the solid matter forms an open network aggregate with many branch points in the primary structure which prevents individual floccules from approaching each other closely, the open network aggregate, over time, forming a loosely packed sediment with a scaffold-like structure and not a solid cake.

There is no requirement in claims 19 and 41 of the '318 patent or in claim 1 of the '320 patent that the surfactant and component (b) each be present in sufficient quantities to form a stable flocculated suspension.

Claim 1 of the '320 patent requires that component (a) and the surfactant be added to the water before the addition of the megestrol acetate.

The court will prepare an order implementing this opinion.

**/s/ Dickinson R. Debevoise**
DICKINSON R. DEBEVOISE
U.S.S.D.J.

Dated: May 25, 2006